



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/778,926	02/06/2001	John Collinge	102286-408CON	8540

23483 7590 08/28/2003

HALE AND DORR, LLP
60 STATE STREET
BOSTON, MA 02109

EXAMINER

CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
----------	--------------

1634

DATE MAILED: 08/28/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/778,926

Applicant(s)
Collinge

Examiner
Arun Chakrabarti

Art Unit
1634



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 27, 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-16, 26, and 28-32 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-16, 26, and 28-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 0603 6) ☒ Other: Detailed Action

Art Unit: 1634

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 27, 2003 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Art Unit: 1634

3. Claims 1-10,13-16,26, and 28-30 are rejected under 35 U.S.C. 102 (e) as being anticipated by Prusiner et al. (U.S. patent 5,846,533) (December 8, 1998).

Prusiner et al teach a method for typing a sample of a prion or spongiform encephalopathy disease or Creutzfeldt-Jakob disease, the method comprising comparing and identifying similar physicochemical properties of the sample with a standard sample of known type (Abstract and Figures 8, 11 and 12 and Example 15 and Column 5, lines 45-62).

Prusiner et al teach a method for assessing and predicting the susceptibility of a human to bovine spongiform encephalopathy or a derivative thereof. (Example 15).

Prusiner et al. teach the sizes and ratios of distinct PrP Sc type glycoforms (Example 13 and Figures 11 and 12).

Prusiner et al teach a method for typing a sample of a prion or spongiform encephalopathy disease. the method comprising comparing and identifying similar physicochemical properties of the sample with a standard sample of known type (Examples 8, 13 and 15).

Prusiner et al teach a method wherein the comparison of physicochemical properties comprises a comparison of protease resistance (Example 15, Column 36, lines 20-37 and Column 12, lines 43-67).

Art Unit: 1634

Prusiner et al teach a method for identifying infection in an animal and tissue of bovine spongiform encephalopathy the method comprising isolating a prion protein from the animal and/or tissue and identifying that the prion protein can be characterized by having three distinct bands on an electrophoresis gel following proteinase K digestion (Figure 11, lanes 9, 11, and 14 and Figure 12, lanes 4, 6, 7, 8, and 12), the bands comprising i) a band of highest molecular weight in the greatest proportion, ii) a band of lowest molecular weight in the lowest proportion, and iii) a band with a molecular weight between I and II and of a proportion between I and II. (Figure 11, lane 9 and Lane 4 of Figure 12).

Prusiner et al teach a method wherein the animal is mammalian and non-bovine (Human to be precise) (Column 4, lines 5-8).

Prusiner et al teach a method for identifying infection in an animal and/or tissue (Abstract).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being obvious over Prusiner et al. (U.S. patent 5,846,533) (December 8, 1998) in view of Race et al. (Bovine Spongiform

Art Unit: 1634

Encephalopathy: The BSE Dilemma, [Proceedings of the International Workshop on Bovine Spongiform Encephalopathy: The BSE Dilemma], 6th, Williamsburg, Va., Feb. 26- Mar. 1, 1995 (1996), 317-324).

Prusiner et al teaches the method of claims 1-10,13-16,26, and 28-30 as described above.

Prusiner et al do not teach the method, wherein the prion is derived from a tissue of the lymphoreticular system selected from spleen or lymph node.

Race et al. teach the method, wherein the prion is derived from a tissue of the lymphoreticular system selected from spleen or lymph node (Abstract and Materials and Methods).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the source of prion as spleen and lymph node of Race et al. in the method for typing a sample of a prion or spongiform encephalopathy disease of Prusiner et al since Race et al. states, "In addition, we showed that detection of Prp-Res in sheep brain, spleen, or lymph node identified more scrapie-positive sheep than could be identified using microscopic evaluation of sheep brain (Abstract)". An ordinary practitioner would have been motivated to substitute and combine the source of prion as spleen and lymph node of Race et al. in the method for typing a sample of a prion or spongiform encephalopathy disease of Prusiner et al. in order to achieve the express advantages, as noted by Race et al., of a source of prion which identified more scrapie-positive sheep than could be identified using microscopic evaluation of sheep brain.

Art Unit: 1634

Response to Amendment

6. In response to amendment, all previous 103(a) rejections are hereby withdrawn. However, new 102(e) and 103(a) rejection has been included.

Response to Arguments

7. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703)605-1237.

Arun Chakrabarti,
Patent Examiner,

August 21, 2003

Arun K. Chakrabarti
ARUN K. CHAKRABARTI
PATENT EXAMINER